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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,470	09/01/2006	Martin Scholz	0060.0002	1446

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,470	SCHOLZ, MARTIN	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-25* is/are pending in the application.

4a) Of the above claim(s) *14,15,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/1/06* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-15 and 18-25 are pending.

2. Applicant's election with traverse of Group II, Claims 1-13 and 18-23 drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is specific antigen from a specific virus, filed 2/11/08, is acknowledged.

The traversal is on the grounds that the present invention teaches leukocyte stimulation matrices for stimulating leukocytes and/or induction of immunological tolerance, wherein "leukocyte stimulation" means that previously conditioned immune cells are specifically enhanced in their immune, response, and "induction of a tolerance" means that an anergy of leukocytes is induced toward a specific antigen, which means that an inactivation takes place. *See* page 2 of present specification. Thus, stimulating or enhancing the immune response of leukocytes and the corresponding induction of tolerance is a technical relationship that links Groups I-XII and distinguishes them from U.S. Application No. 2003/0129214. However, U.S. Application No. 2003/0129214 teaches methods for enhancing the biocompatibility of a medical device implanted within a living portion of the body, comprising contacting a portion of a living body that is in contact with an implanted medical device with a specific monocyte chemoattractant protein (MCP-1) antagonist to inhibit chronic inflammation induced by the presence of the medical device or fibrous encapsulation of the medical device. *See* page 1, para. [0006]. The MCP-1 antagonist polypeptide inhibits MCP-1 (a chemoattractant cytokine known to promote the migration and activation of monocytes) protein expression in the portion of a living body which contacts the implanted medical device. *See page4,* para, [0037]. In other words, the MCP-1 antagonist polypeptide inhibits or suppresses MCP-1 protein activity, which would otherwise promote monocyte (leukocyte) activity, to enhance the biocompatibility of a medical device implanted into any living body.

Applicants' traversal has been fully considered but is not deemed persuasive for the following reasons.

The inventions listed as Inventions 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among Inventions 1-12 is a leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of an immunological tolerance having the following components: a) at least one carrier, b) a soluble matrix for embedding at least one component for generating a leukocyte stimulation and/or the induction of an immunological tolerance, c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance.

However, the US application 2003/0129214 A1 (published July 10, 2003 1996; PTO 892) teaches leukocyte stimulation matrix for induction of immunological tolerance comprising at least one carrier such as polyurethanes or biological material such as tendon or dermal collagen (see page 8, paragraphs 0070-0071, in particular), a soluble matrix from any suitable material such as hydrogel coated onto said carrier for embedding at least one component such as MCP-1 antagonist for induction of immunological tolerance such as inhibition of chronic inflammation at the site of implantation (see page 8, paragraphs 0074, page 3, 0034, claims 25-38 of application, in particular). Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fec. Cir. 1990). See MPEP 2112.01. Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1-9 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Therefore, the requirement of Group II and Groups I and III-XII is still deemed proper and is therefore made FINAL.

3. Claims 14-15, 24 and 25 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 1-13 and 18-23, drawn to leukocyte stimulation matrix for the stimulation of leukocytes and/or the induction of immunological tolerance having a) at least one carrier, b) a soluble matrix

and c) at least one component embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of an immunological tolerance wherein the component for generating leukocyte stimulation and/or induction of tolerance is specific antigen from a specific virus are being acted upon in this Office Action.

5. Claims 1 is objected to because the article "A" is missing for said claim.

6. Claims 2-13 and 18-23 are objected to because the article "The" is missing for said dependent claims.

7. Claims 4-6 are objected to for reciting non-elected embodiments.

8. Claims 7-8 are objected to because "combinations thereof" should have been "a combination thereof".

9. Claim 21 is objected to because the word "anydroxyalkyloxy silance" is misspelled. It should have been "an**h**ydroalkoxy silane" or anhydride alkoxysilance", see specification at page 13 first paragraph.

10. Applicant is advised that should claim 13 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

11. The drawings are objected to because Figures are poor quality and slanted. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from

the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

12. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

13. The disclosure is objected to because of the following informalities: the word "ararose" at page 13 line 4 is misspelled. It should be "agarose", and the Brief Description of the Drawing is missing.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-13 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) any leukocyte stimulation matrix comprising any carrier, any soluble matrix, any one or more "components" embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of immunological tolerance, (2) any synthetic antigen from any virus, (3) any co-stimulatory factors obtained from endogenous tissue, cell cultures, and/or synthetically, (4) any "component" for generating leukocyte stimulation or any fragment of any virus of the family of herpes, for generating leukocyte stimulation and/or induction of any immunological tolerance.

The specification discloses only the specific biocompatible materials as a carrier selected from the group consisting of polyurethanes, polycarbonates, polystyrene, Monocryl (poliglecaprone 25, PDS-2 (polydioxanon), Maxon (polyglyconate), Vicryl (polyglactin-910), Dexon-Plus (polyglycolic acid), glass, gut skins, or sponges, see page 5-6. The specification discloses the soluble matrix is made of polyethylene glycol (PEG) or a matrix comprising PEG and a long chain sugar compound selected from the group consisting of starch, cellulose and glycogen. The soluble matrix preferably comprises 50-90 wt.%, more preferably 60-80 wt.% of one or more long chain sugar compounds and 10-50 wt.%, preferably 20-40 wt.% of a polyethylene glycol, based on the total of long chain sugar compounds and polyethylene glycol, see page 7 of specification. PEG is preferably used as an aqueous solution, wherein a solution of about 1-10 wt.%, preferably about 5 wt.%, of a PEG having e.g. a molecular weight of 15-20 kD is used. The concentration can be up to 20 wt.% of a PEG with a low molecular weight (e.g.

about 6 kD), see page 7. The specification discloses antigen from virus (CMV) is embedded or covalantly linked to polyethylene glycol (PEG) using coupling agent anhydroalkoxysilance also known as 3-triethoxysilyl propyl succinic acid anhydride (GENIOSIL®), covalent bond selected from the group consisting of cyanogen bromide, cyanoborao hydride, agarose, silance and a combination thereof, see page 13.

The specification exemplifies a leukocyte stimulation matrix comprising a) 10 mg of polyurethane foam as a carrier, b) a solution of polyethylene glycol having a molecular weight of 15-20 kd, and c) UV-inactivated cytomegalovirus virus antigen embedded into polyethylene glycol, see page 19 or UV-inactivated cytomegovirus antigen covalently bounds to the carrier polyurethane foam using coupling agent 3-triethoxysilyl propyl succinic acid anhydride (GENIOSIL®). The carrier with covalently bound antigens showed a decreasing immune reaction (CD69/INF-γ). In contrast, the antigens embedded in the soluble matrix could induce antigen specific T-cell mediated immune response in whole blood was constant over time.

However, the specification does not disclose any and all leukocyte stimulation matrix comprising any carrier, any soluble matrix, and any one or more components embedded into the soluble matrix for generating a leukocyte stimulation and/or the induction of immunological tolerance other than the specific carrier mentioned above, the specific coupling agent such as the ones recited in claims 8-9, 21, the specific soluble matrix such as the ones recited in claims 11 and 22, and the specific viral antigen. The specification does not disclose the soluble matrix is made of only starch, cellulose, or glycogen as set forth in claim 10 for the claimed leukocyte stimulation matrix. The specification discloses PEG is a mandatory components of the soluble matrix, see page 6, last paragraph. There is no disclosure of any leukocyte stimulation matrix that could induce tolerance in light of viral antigen or viral antigen coupled to carrier as exemplified in the specification. There is no disclosure of any leukocyte stimulation matrix that stimulate leukocyte *and* induce any immunological tolerance in light of viral antigen or viral antigen coupled to carrier as exemplified in the specification. On the contrary, the specification discloses immune tolerance can be achieve using a respective matrix in which inhibitory factors are embedded, or by adding inhibitory factors into the module during leukocyte stimulation, see page 16.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

As discussed above, the skill artisan cannot envision the detailed structure of the encompassed genus of "component", carrier, soluble matrix for the claimed leukocyte stimulation matrix that either stimulation of leukocyte, or induction of an immunological tolerance, or stimulation of leukocyte and the induction of any immunological tolerance.

Adequate written description requires more than a mere statement that it is part of the invention. The antagonist itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provides only the bovine sequence. In this case, the specification provides the murine and human sequences, and seeks coverage for methods of using any protein that is functionally equivalent to such and would be encoded by a polynucleotide that would hybridize under unspecified conditions to a reference molecule.

Therefore, only leukocyte stimulation matrix comprising the specific carrier, the specific soluble matrix and the specific CMV viral antigen that stimulate leukocyte meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

17. Claims 8, 11 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "coupling component" in claim 8 has no antecedent basis in base claim 2 because the word "coupling" is not recited in claim 2.

Claims 11 and 22 are indefinite because the metes and bound of the weight % of the long chain sugar compound cannot be determined since the molecular weight of such sugar depends on the total length of the sugar chain.

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 5,529,777 (issued June 25, 1996; PTO 892).

The '777 patent teaches a leukocyte stimulation matrix comprising a soluble matrix such as a water soluble polymers or polymeric hydrogels for embedding at least any antigen, at least one component embedded into the soluble matrix for generating a leukocyte stimulation to such antigen such as influenza virus or component of viral antigen such as viral particle structural components that elicit protective immunity (see abstract, col. 12, line 25-67, in particular), at least one carrier such as albumin or hapten (see col. 12, line 35-38, in particular) and at least one component such that mediating the binding between the reference albumin or hapten and the reference viral antigen or component of viral antigen wherein the component is covalent bonding by crosslinking known to those skilled in the art (see abstract, col. 12, lines 35-36, col. 14, line 44-50, col. 11, lines 48-51, in particular). The reference viral antigen can be synthetic using recombinant technology (see col. 12, lines 54-61, in particular). The reference carrier can be polyurethanes or polycarbonates (see col. 4, lines 1-10, in particular). The reference soluble matrix is made of alginate, gelatin, pectin, collagen, polyethylene glycol (see summary of invention, col. 5, lines 9-14, in particular) or cellulose (see col. 4, line 35, in particular). The reference matrix inherently stimulates leukocytes since it is used as a vaccine. Further, products of identical chemical composition cannot have mutually exclusive properties. A chemical

composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fec. Cir. 1990). See MPEP 2112.01. Finally, a product is a product, irrespective of its intended use such as for stimulation and/or the induction of an immunological tolerance. Thus, the reference teachings anticipate the claimed invention.

20. Claims 1, 4-6, 12-13, 18 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 2004/006951 publication (published January 22, 2004; PTO 1449).

The WO 2004/006951 publication teaches a leukocyte stimulation matrix comprising a housing having at least one inlet opening and at least one outlet opening such as a tube (see paragraph 37, in particular), the matrix can be made of organic material such as cellulose (see page 12, paragraph 39, in particular) coated with at least one leukocyte stimulation component such as at least one viral antigen including herpes simplex virus or cytomegalovirus virus (CMV) or a synthetic CMV peptide NLVPMVATV of SEQ ID NO: 4 that engaged in a unique clonotypic lymphocyte receptor (see paragraph 7, paragraph 107, paragraph 158, in particular), at least one component for generating leukocyte stimulation and/or induction of tolerance such as lymphocyte affecting molecule such as T cell co-stimulatory molecule CD80 or CD28 for stimulating cytotoxic cells or apoptosis inducing molecule for induction of tolerance (see claim 24 of the publication, page 10, paragraph 32, in particular), a carrier such as human serum albumin or lysine and alanine (see page 15, paragraph 46, page 13, paragraph 40, in particular). Thus, the reference teachings anticipate the claimed invention. Thus, the reference teachings anticipate the claimed invention.

21. Claims 1-3, 7-9, 12-13, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 5,663,051 (issued Sept 2, 1997; PTO 892).

The ‘051 patent teaches a leukocyte stimulation matrix comprising a housing having at least one inlet opening and at least one outlet opening such as a cell trap tube (see figure, col. 11, line 21-47, in particular) comprising a soluble matrix such as density gradient cell separation medium such as sucrose, dextran, bovine serum albumin (see col. 13, lines 24-27, in particular) or polyethylene glycol (PEG) matrix (see col. 15, in particular), a carrier such as polystyrene latex particle (see col. 17, line 37, in particular), silica bead (see col. 17, line 13, in particular), glass (col. 16, line 65, in particular), cellulose (see 16, line 66, in particular), long chain sugar such as

polysaccharide or agarose, cellulose, sepharose, Sephadex etc. or a combination thereof (see col. 16, line 65-67, in particular), a coupling agent such as silane group with alkyl trimethoxy silane to the silica particle (see col. 13, lines 60 bridging col. 14, lines 1-10, in particular), carbodiimide or alkyl halide (see col. 19, lines 64 through col. 20, lines 1-6, in particular) and at least one component that embedded into the soluble matrix that stimulate leukocyte such as IFN-α or β (see col. 18, lines 41-43, in particular), or TGF-β (see col. 18, line 42, in particular). The reference carrier and at least one component for generating leukocyte stimulation is via covalent binding (see col. 19, line 45-46, in particular). Thus, the reference teachings anticipate the claimed invention.

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. Claims 1, 7, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over as being anticipated by US Pat No 5,529,777 (issued June 25, 1996; PTO 892) in view of WO 96/27657 (published Sept 1996; PTO 1449).

The teachings of the '777 patent have been discussed supra.

The invention in claim 19 differs from the teachings of the reference only in that the soluble matrix wherein the carrier is made of natural material gut skin.

The invention in claim 20 differs from the teachings of the reference only in that the soluble matrix wherein the carrier is made of sponge.

The WO 96/27657 publication teaches various carrier or substrates made of biocompatible materials such as glass (see page 9, line 14, in particular), biodegradable polymer such as sponge (see page 9, line 29, in particular) and skin equivalent (see page 16, line 15-20, references cited therein, in particular). The WO 96/27657 publication further teaches soluble matrix or carrier such as polyethylene oxide, polyvinyl alcohol, methacrylate, polyacrylamide, natural polymer such as hyuronic acid, carboxymethylcellulose, and starch (see paragraph bridging pages 6 and 7, in particular). The reference soluble matrix is embedded with a

component such as growth factor EGF, TGF-beta, cytokines such as interleukins, GM-CSF, hormone or insulin covalently attached to the matrix or carrier known to one of ordinary skill in the Art (see page 11-12, in particular). The WO 96/27657 publication teaches the reference soluble polymer matrix polyethylene oxide (PEO) is about 97% and 3% of DVB by weight, see page 7, in particular). The advantage of using natural material is that the biodegradability of the polymer can be used to regulate the length of time the growth factor stimulate growth or effect on the cell (see page 10, first paragraph, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the soluble matrix polymeric hydrogels of the '777 patent for the natural material such as the gut skin or the sponge as taught by the WO 96/27657 publication for leukocyte matrix comprising a soluble gut skin or sponge embedded with viral antigen tethered to matrix or carrier such as polyethylene oxide, polyvinyl alcohol, methacrylate, polyacrylamide, natural polymer such as hyuronic acid, carboxymethylcellulose, or starch as taught by the '777 patent and the WO 96/27657 publication.

One having ordinary skill in the art would have been motivated to do this because the advantage of using natural material is that the biodegradability of the polymer can be used to regulate the length of time the growth factor stimulate growth or effect on the cell as taught by the WO 96/27657 publication (see page 10, first paragraph, in particular). The '777 patent teaches a leukocyte stimulation matrix comprising a soluble matrix such as a water soluble polymers or polymeric hydrogels for embedding any antigen, at least one component embedded into the soluble matrix for generating a leukocyte stimulation to such antigen such as influenza virus or component of viral antigen such as viral particle structural components that is useful for stimulating or eliciting protective immunity against the virus (see abstract, col. 12, line 25-67, in particular).

24. Claims 1, 10 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 5,663,051 (issued Sept 2, 1997; PTO 892).

The teachings of the '051 patent have been discussed supra.

The invention in claim 11 differs from the teachings of the reference only in that the soluble matrix is made of 50-90% of a long chain sugar compound and 10-50 % by weight of polyethylene glycol based on the total of long chain sugar compound and polyethylene glycol.

The invention in claim 22 differs from the teachings of the reference only in that the soluble matrix is made of 60-80% of a long chain sugar compound and 40-20 wt % of polyethylene glycol based on the total of long chain sugar compound and polyethylene glycol.

It is within the purview of one of ordinary skill in the chemistry art to mix any desire ratio of long chain sugar such as 50 % to 90% of sucrose or dextran by weight (see col. 13, lines 24-27, in particular) with 10 to 50 % of polyethylene glycol (PEG) by weight based on the total weight (100%) of long chain sugar and polyethylene glycol.

25. No claim is allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9: 00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B O'Hara can be reached on (571) 272-0878. The IFW official Fax number is (571) 273-8300.

27. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Primary Examiner, Art Unit 1644
March 28, 2008